REMARKS

In the Office Action dated March 12, 2001, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following three separate and distinct inventions:

I. Claims 1-33, 35, 40 and 41, drawn to Il-16 antagonist peptides, nucleic acids encoding, and pharmaceutical compositions, classified in class 536, subclass 23.1, for example.

II. Claims 34 and 36, drawn to antibodies and pharmaceutical compositions thereof, classified in class 530, subclass 387.9, for example.

III. Claims 37-39 and 42, drawn to methods of treatment, classified in class 514, subclass 2.

In addition, the Examiner contends that claims 1and 40-42 are generic to a plurality of disclosed patentably distinct species comprising SEQ ID NO: 1-32 and 34-38, each SEQ ID NO: being a distinct species. The Examiner requires Applicants to elect a single disclosed species.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1-33, 35 and 40-41, directed to Il-16 antagonist peptides, nucleic acids encoding Il-16 antagonist peptides, and pharmaceutical compositions. Furthermore, Applicants provisionally elect SEQ ID NO: 2 in response to the requirement for species election. Claims which read on the elected species include claims 1-2, 6-9, 12-13 and 33-42. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more <u>independent and distinct</u> inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the first instance, Examiner asserts that the peptides of Group I and the antibodies of Group II are distinct inventions because peptides and antibodies are physically and functionally distinct chemical entities and because they can be used in different processes. The Examiner further asserts that the nucleic acid molecules of Group I are distinct and unrelated to the antibodies of Group 2 because nucleic acid molecules and antibodies are physically and structurally distinct chemical entities.

Applicants respectfully submit that the peptides and nucleic acid molecules of Group I are clearly related to the antibodies of Group II. The antibodies of Group II are specific for the peptides of Group I, and thus can be readily prepared once the peptide sequence or the peptide-encoding nucleotide sequence is provided. Thus, the antibodies of Group II are not independent or distinct from the peptides and nucleic acid molecules of Group I.

The Examiner also admits that Groups I and III are related as product and process of use. However, the Examiner contends that Groups I and III are distinct since, e.g., the peptides of Group I can be used in a method different from the methods of treatment of Group III. The Examiner further contends that the antibodies of Group II are separate and distinct from the methods of Group III, since the antibodies are neither made by nor used in the methods of Group III.

Applicants respectfully submit that Groups I, II and III are merely different aspects of a single invention. The methods of Group III demonstrate how to use the peptides of Group I. The antibodies of Group II can be used to detect or purify the peptides of Group I. The courts have recognized that it is in the public interest to permit applicants to claim several aspects of

their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q.

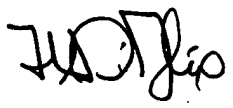
2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined three groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims, or at least the claims of Groups I and II.

Respectfully submitted,



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